REMARKS

In the Office Action, claims 1-3, 5, 11, 15-19, 24, 28, 29, 44-47, 52 and 55-57 are rejected under 35 U.S.C. § 102 or, in the alternative, under 35 U.S.C. § 103 in view of U.S. Patent No. 5,122,516 ("*Watanabe*"); and claims 1-72 are rejected under 35 U.S.C. § 103 in view of *Watanabe* and U.S. Patent No. 4,630,727 ("*Feriani*") and *van Bommel*. Thus, the Patent Office rejects the claimed invention as defined by claims 1-3, 5, 11, 15-19, 24, 28, 29, 44-47, 52 and 55-57 in view of *Watanabe*, on its own, or further rejects these claims in addition to the other remaining claims in view of *Watanabe* and further in view of the remaining cited art. Applicants believe that the rejections are improper for the reasons set forth below.

At the outset, clearly the anticipation rejection or, in the alternative, the obviousness rejection, in view of *Watanabe*, on its own, is improper. Indeed, the Patent Office further relies on two additional references in combination with *Watanabe* to reject the same claims. See, Office Action, page 4. Clearly, this suggests that *Watanabe*, on its own, is deficient with respect to the claimed invention and thus the anticipation and obviousness rejections based solely on *Watanabe* should be withdrawn for at least these reasons.

Further, Applicants believe that *Watanabe*, alone or even if combinable with the remaining cited art, fails to disclose or suggest at least a number of features of the claimed invention. Of the pending claims, claims 1, 17, 30, 44, 55 and 64 are the sole independent claims. Claim 1 recites a two part dialysis solution that includes a first component including a bicarbonate concentrate and a second component including an electrolyte concentrate wherein each of the first component and the second component include a physiological acceptable amount of sodium. Claim 17 recites a two part dialysis solution that is designed to be infused into a patient. The solution includes a first component that includes a bicarbonate concentrate not including potassium and a second component including an electrolyte concentrate that includes potassium wherein the first component and the second component are so constructed and arranged that the second component physically cannot be infused into the patient without mixing with the first component.

Claim 30 recites a two part dialysis solution that includes a first component including a bicarbonate concentrate and a second component including an electrolyte concentrate wherein each of the first component and the second component include a physiological acceptable amount of potassium. Claim 44 recites a method of providing hemofiltration to a patient. The

method includes providing a first component including a bicarbonate concentrate and a second component including an electrolyte concentrate wherein each of the first component and the second component include a physiological acceptable amount of sodium; mixing the first component and the second component to form a mixed solution; and using the mixed solution during hemofiltration.

Claim 55 recites a method of providing hemofiltration to a patient. The method includes providing a first component including a bicarbonate concentrate that does not include potassium and a second component including an electrolyte concentrate that includes potassium; orienting the first component and the second component so that the second component physically cannot be infused into the patient without mixing with the first component; mixing the first component and the second component to form a mixed solution; and infusing the mixed solution into the patient. Claim 64 recites a method of providing hemofiltration to a patient. The method includes providing a first component including a bicarbonate concentrate and a second component including an electrolyte concentrate wherein each of the first component and second component include a physiological acceptable amount of potassium; mixing the first component and the second component to form a mixed solution; and using the mixed solution during hemofiltration.

The bicarbonate-based solutions of the present invention can include a number of constituents or components that are separately housed such that the components can be readily and sterily mixed to form the resulting bicarbonate-based solution. Applicants have discovered that the bicarbonate-based solutions of the present invention can eliminate the need of excessive handling of one more of its components prior to mixing as compared to conventional solutions which necessarily require a physician or other medical care provider to manually inject one or more components, such as bicarbonate, potassium chloride and the like, during the formulation of a bicarbonate solution.

In this regard, the ready-to-use bicarbonate based formulations of the present invention can increase the amount of time and effort with respect to the preparation and administration of the formulations of the present invention as compared to conventional bicarbonate formulations. The ready-to-use formulations of the present invention can also effectively eliminate, or at least greatly minimize, the potential of the spread of biological contamination during the preparation, administration and/or general use thereof. Such attributes of the bicarbonate-based formulations

of the present invention are desirable as applied in medical therapies, particularly in an intensive care setting. See, Specification, page 7, lines 4-20.

In contrast, the *Watanabe* reference is clearly deficient with respect to the claimed invention. For example, the *Watanabe* reference is deficient with respect to a two part dialysis solution that includes potassium in each component part as required by the claimed invention (see, for example, claims 30 and 64) and as even admitted by the Patent Office.

Further, Applicants believe that the *Watanabe* reference is deficient with respect to a two part dialysis solution that includes a physiological acceptable amount of sodium in each part, such as in equimolar amounts, as required by the claimed invention. Indeed, the only source of sodium in the second composition of *Watanabe* is provided from sodium hydrogen carbonate. See, *Watanabe*, column 8, lines 56-61. Moreover, the amount of sodium in the second composition is much less than the amount of sodium in the first composition. In this regard, *Watanabe* merely discloses an amount of sodium in the second composition from 15 to 40 mmols, preferably 20 to 30 mmols. See, *Watanabe*, column 8, lines 1-64.

This clearly contrasts the claimed invention. For example, claim 1 recites a two part dialysis solution with first and second components that each include a physiological acceptable amount of sodium. The amount of sodium can include equimolar amounts, such as about 160 mmol/L or less, including from about 100 mmol/L to about 160 mmol/L as further defined by the claimed invention. The amount of sodium in the bicarbonate component can be derived from sodium bicarbonate ($NaHCO_3$) in addition to other sodium sources, such as sodium chloride as disclosed in the specification, for example, in examples 1 and 2. Again, the sole source of sodium in the second composition of *Watanabe* is provided from sodium hydrogen carbonate that merely produces from about 15 to 40 mmols of sodium.

With respect to potassium, indeed, *Watanabe* merely discloses potassium in the first composition as an optional ingredient. For example, *Watanabe* discloses potassium in an amount from 0 to 4 mmols in the first composition. See, *Watanabe*, column 8, lines 3-20. In contrast, the claimed invention (see, for example, claims 17, 30, 55 and 64) at least includes potassium in the electrolyte concentrate. As further defined, the claimed invention can include sodium in both parts in addition to potassium wherein the sodium is provided in equimolar and/or physiological amounts, such as about 160 mmol/L or less. Based on at least these

reasons, clearly one skilled in the art would consider *Watanabe* to be deficient with respect to the claimed invention.

Further, Applicants do not believe that the Patent Office can rely solely on *Feriani* and *van Bommel* to remedy the deficiencies of *Watanabe.* Indeed, nowhere do the teachings of *Feriani* and/or *Van Bommel* suggest that potassium can be included in both the bicarbonate and electrolyte parts as required by the claimed invention and as even admitted by the Patent Office. See, Office Action, page 5. Moreover, the Patent Office merely relies on *van Bommel* as allegedly teaching that hemodialysis and continuous renal replacement therapy can use the same fluids; and also relies on *Feriani* as allegedly teaching a two part composition that is contained in a two chamber bag in which the first chamber is filled with a bicarbonate-containing fluid that allegedly can include potassium and the second container is filled with an acid fluid. See, Office Action, page 4.

What the Patent Office has done is to rely on hindsight reasoning in support of the obviousness rejection. This is clearly improper. Again, *Watanabe* is deficient with respect to at least a number of features of the claimed invention. Moreover, the Patent Office attempts to remedy the numerous deficiencies of *Watanabe*, alone or combined with the remaining art, with mere conclusions that are unsupported based on the cited art that has been relied on to date. Therefore, Applicants do not believe that one skilled in the art would be inclined to modify *Watanabe* in view of the other cited art to arrive at the claimed invention.

Based on at least these differences between the claimed invention and the cited art, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art, alone or even if combinable, fails to anticipate or render obvious the claimed invention.

Accordingly, Applicants respectfully request that the anticipation and obviousness rejections be withdrawn.

Applicants note for the record that the Patent Office has refused to examine and enter a number of foreign patents that were listed on Applicants previously-submitted Information Disclosure Statement. See, Office Action, pages 2 and 3. In response, Applicants are submitting herewith a Supplemental Information Disclosure Statement with the foreign patents listed and not previously entered. Along with the Supplemental Information Disclosure Statement, Applicants are submitting herewith a copy of each of the foreign patent documents as requested

by the Patent Office in addition to English language abstracts regarding same. Accordingly, Applicants respectfully submit that the foreign patent documents listed therein be entered and examined during prosecution of the present application.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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